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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,366	12/27/2001	Noel John De Souza	U 013784-9	7802

140 7590 12/17/2002

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	6

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/033,366	De Souza et al.
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 27, 2001* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-31* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 3, drawn to a method of treatment of a health condition associated with modulation of immunity which method comprises administering a standardized herbal extract prepared from the plant *Tinospora cordifolia*, classified in class 424, subclass 769 or class 514, subclass 885.

II. Claims 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 25 and 27-28, drawn to a method of treatment of a health condition associated with modulation of immunity which method comprises administering a standardized herbal extract prepared from the plant *Tinospora cordifolia* in conjunction with another treatment for the health condition, classified in class 424, subclass 769 or class 514, subclass 885.

III. Claims 5, 8, 11, 14, 17, 20, 23 and 26-28, drawn to a method of treatment of a health condition associated with alteration or modulation of immunity which method comprises administering a standardized herbal extract prepared from the plant *Tinospora cordifolia* having defined immunomodulatory activity in conjunction with another therapy for the health condition, classified in class 424, subclass 769 or class 514, subclass 885.

IV. Claim 29, drawn to a process for preparation of a standardized extract of *Tinospora cordifolia* which comprises treating plant material with water at an elevated temperature, filtering and concentrating, classified in class 424, subclass 769 or class 724, subclass 725.

V. Claims 30-31, drawn to an extract of *Tinospora cordifolia*, classified in class 424, subclass 769.

2. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the five different groups are directed to five different inventions. The invention of Group I differs from the inventions of Group II-IV because the invention of Group I is directed to a method to a method of treatment of a health condition comprising administering a standardized extract of *Tinospora cordifolia*, whereas the invention of Group II is directed to a method of treatment of a health condition comprising administering a standardized extract of *Tinospora cordifolia* in conjunction with another treatment for the health condition, whereas the invention of Group III is directed to a method of treatment of a health condition associated with alteration or modulation of immunity comprising administering a standardized extract of *Tinospora cordifolia*, wherein the extract is standardized on the basis of defined immunomodulatory activity; and, whereas the invention of Group IV is directed to a process of making a standardized extract of *Tinospora cordifolia* comprising treating the plant material with water an elevated temperature, filtering and

concentrating. The three methods of treatments comprise the administration of ingredients which are not necessarily the same, and the administration of ingredients either alone or in conjunction with other materially different treatments and/or therapy for the same health condition. The administration of different ingredients are expected not to have the same functional effect. Moreover, the several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

3. Inventions III and V are related as process and product of use The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed has been found useful in the treatment of a various health conditions not related to modulation or alteration of immunity per se, as evidenced by the claims themselves. Moreover, the process for using the product as claimed can be practiced with another materially different product. For instance, in US 5,077,284, Loria et al. teach administering dehydroepiandrosterone to improve immune response.

4. Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process, as evidenced by the claims themselves. For instance, as drafted, the invention of Group IV is directed to a process of preparing a standardized extract of *Tinospora cordifolia* comprising treating the plant material with water an elevated temperature, filtering and concentrating, whereas the process of preparing the product-by-process of the invention of Group V treating pulverized above ground parts of plant material of *Tinospora cordifolia* with water at an elevated temperature, filtering and concentrating. Thus, the claimed product can be made by more than one method involving different process steps and materially different ingredients (i.e., whole plant versus above ground parts of the plant).

5. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood.

MCF

December 13, 2002